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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,032	06/29/2001	Christoph Seidel	HUBR-1067.3 DIV	2111

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EXAMINER	
BROWN, TIMOTHY M	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/896,032	SEIDEL ET AL.	
	Examiner	Art Unit	
	Tim Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *40-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to Applicants' Amendment After Final mailed March 15, 2004. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. Claims 1-39 and 49 have been canceled. Claims 40-48 are pending.

Please note the Examiner of Record in this application has changed to Tim Brown. The Examiner makes the following observations with regard to the pending claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an HCV assay using the entire NS3 antigen under reducing conditions, does not reasonably enable an assay using the various embodiments of the NS3 antigen claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

"Undue experimentation" is defined by a number of factors including the breadth of the claims, the level of predicatability in the art, the existence of working examples, and the quantity of experimentation that is needed to make and use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404.

Applicants' invention is an immunoassay for detecting the presence of HCV-specific antibodies in a patient sample. The immunoassay relies on the interaction of HCV-specific antibodies with a polypeptide consisting of "an amino acid sequence found in hepatitis C virus protein NS3 region" (claim

40, lines 6-7). The polypeptide is modified at one or more cysteine residues and the patient sample is collected under reducing conditions.

Undue experimentation would be required in order to make and use an HCV assay wherein the polypeptide merely consists of a portion of the NS3 region as claimed. This results because one of ordinary skill could not predict the full range of NS3 amino acid sequences that would actually react with HCV-specific antibodies. Applicants have also failed to provide any working examples wherein only a portion of the NS3 polypeptide was used for the early detection of HCV-specific antibodies.

Undue experimentation is also required to make and use an HCV assay wherein the NS3 polpypeptide is modified at one or more cysteine residues. Cysteine residues are critical to the conformation of the NS3 polypeptide since they provide for disulfide bridging. Thus, removing cysteine residues would change the conformation of the NS3 polypeptide and destroy its ability to react with HCV-specific antibodies. The skilled artisan could not possibly predict which cysteine modifications would permit the NS3 polypeptide to react with HCV-specific antibody. Accordingly, undue experimentation would be required in order to use an HCV assay wherein the NS3 polpypeptide is modified at one or more cysteine residues.

Claims 43, 46 and 47 require undue experimentation for the additional reason that they are drawn to specific unsupported NS3 polypeptides. As understood by the Examiner, claim 43 states that the NS3 polypeptide consists of (1) amino acids 21-282 of SEQ ID NO:9 having a sequence of 20 amino acids joined thereto, or (2) a protein with 90% homology to the NS3 polypeptide. Applicants have failed to provide a working example for either NS3 polypeptide. Moreover, portions of an immunoreactive protein do not necessarily share the reactivity of the protein from which they are derived.

For at least the foregoing reasons, Applicants' specification fails to enable one of ordinary skill in the art to use the full scope of the invention without undue experimentation. Claims 40-48 therefore fail to satisfy the enablement requirement.

Claims 43, 46 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the present case, Applicants claim a method for determining HCV specific antibodies based on the incubation of a human sample with an NS3 polypeptide consisting of (1) amino acids 21-282 of SEQ ID NO:9 having a sequence of 20 amino acids joined thereto, or (2) a protein with 90% homology to the NS3 polypeptide. However, the specification as filed does not disclose the claimed polypeptides having 90% homology to the NS3 polypeptide. The specification must describe the claimed subject matter in terms that establish the applicant was in possession of the claimed invention, including all of the invention's elements and limitations. University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886, 1894 (CAFC 2004). Here, Applicants have failed to establish possession of all the invention's elements and limitations since there is no disclosure of the polypeptides that share 90% homology with NS3. Thus, claims 43, 46 and 47 fail the written description requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40 and 43 are indefinite in their incubation step. The claims recite "incubating a human sample . . . taken from a subject under reducing conditions which prevent the formation of . . . molecular

aggregates with at least one polypeptide consisting of . . . ." This language is indefinite because it is unclear whether (1) the reducing conditions prevent the formation of molecular aggregates with the at least one polypeptide, or (2) the human sample is incubated with the at least one polypeptide, wherein the sample was taken under reducing conditions that prevent the formation of molecular aggregates.

Claim 47 recites "incubating a human sample . . . with at least one polypeptide . . . wherein said polypeptide consists of (a) at least amino acids 21-282 of SEQ ID NO:9 and (b) a contiguous sequence of less than 20 amino acids . . . wherein (b) has been concatenated to the N or C terminus of (a), or an isolated polypeptide which is at least 90% homologous thereto . . . ." This language permits one of two interpretations of "said polypeptide."

First, "said polypeptide" may consist of amino acids 21-282 of SEQ ID NO: 9, wherein the 20 or less amino acids is concatenated to (1) the N terminus of (a), (2) the C terminus of (a), or (3) an polypeptide that is 90% homologous to the 20 or less amino acids. Thus, it is unclear where the 20 or less amino acids are concatenated to.

Second, "said polypeptide" may consist of (1) the combination of (a) and (b), or (2) an isolated polypeptide with 90% homology to the amino acid sequence found in HCV NS3 region (see lines 5-7). The structure of "said polypeptide" is therefore unclear. Appropriate correction of the claims is required.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tim Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tim Brown
Examiner
Art Unit 1648

tb

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 8/9/04